DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology, Incorporated
Ms. Jeanine Redden
Director, Regulatory Affairs
1023 Cherry Road
Memphis, Tennessee 38117

March 5, 2015

Re: K141740
Trade/Device Name: INBONE and INFINITY Total Ankle System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: January 17, 2015
Received: February 3, 2015

Dear Ms. Redden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K141740

Device Name

INBONE and INFINITY Total Ankle System

Indications for Use *(Describe)*

The INBONE and INFINITY Total Ankle is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint. indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

The INBONE and INFINITY Total Ankle is additionally indicated for patients with a failed previous ankle surgery.

CAUTION: The ankle prosthesis is intended for cement use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Wright Medical Technology, Inc.

1023 Cherry Road Memphis, TN 38117

www.wmt.com

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the INBONE® and INFINITY® Total Ankle Systems.

(a)(1).	**Submitted By:**	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
	Date:	March 4, 2015
	Contact Person:	Jeanine Redden Director, Regulatory Affairs Office (901) 867-4522 Fax (901) 867-4190
(a)(2).	**Proprietary Name:**	Inbone® Total Ankle System; Infinity® Total Ankle System
	Common Name:	Total Ankle System
	Classification Name and Reference:	21 CFR 888.3110 - Class II
	Device Product Code, Device Panel:	HSN - Orthopedic
(a)(3).	**Predicate Device:**	K123059 Inbone® II Total Ankle System K123954 and K140749 Infinity® Total Ankle System

(a)(4). Device Description

The Inbone® and Infinity® Total Ankle Systems consist of tibial trays, talar domes and tibial inserts. The tibial trays and talar domes have modular stem connections. The tibial trays are manufactured from titanium alloy; the talar domes are manufactured from cobalt chrome; and the tibial inserts are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE).

The Inbone® and Infinity® Total Ankle Systems are intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint.

The design features of the Inbone® and Infinity® Total Ankle Systems are substantially equivalent to the design features of other-devices previously cleared for market.

(a)(5). Intended Use

The Inbone® and Infinity® Total Ankle Systems are intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint.

Indications for Use

The Inbone® and Infinity® Total Ankle Systems are indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

The Inbone® and Infinity® Total Ankle Systems are additionally indicated for patients with a failed previous ankle surgery.

CAUTION: The ankle prosthesis is intended for cement use only.

The indications are similar to the legally marketed predicate device.

(a)(6). Technological Characteristics Comparison

No design modifications are being made to the subject Inbone® and Infinity® Total Ankle Systems. Modification of the Instructions For Use (IFU) were made include a statement regarding the compatibility of the device with MR environments.

(b)(1). Substantial Equivalence- Non-Clinical Evidence

Testing in a MR environment has found that the subject device poses minimal risk under labeled conditions of use with regard to radio frequency heating or magnetically induced displacement.

(b)(2). Substantial Equivalence- Clinical Evidence

N/A

(b)(3). Substantial Equivalence- Conclusions

As no design changes are being made to the subject device, the design characteristics of the subject device does not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k) regarding testing in a MR environment, the subject device is expected to pose minimal risk under labeled conditions of use to patients when place in an MR environment and is categorized as MR Conditional.